Translation

25 APR 2005

PCT/FR2003/003221

PATENT COOPERATION TREATY

PCT 10/552222

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H273150MN1MP	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/003221	International filing date (*day/month/year*) 29 octobre 2003 (29.10.2003)	Priority date (*day/month/year*) 30 octobre 2002 (30.10.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/00		
Applicant STATICE SANTE		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28 mai 2004 (28.05.2004)	17 March 2005 (17.03.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/003221

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-19, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages 1-11, filed with the letter of 10 February 2005 (10.02.2005)

☒ the drawings:

pages 1/10-10/10, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR 03/03221

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11	YES
	Claims		NO
Inventive step (IS)	Claims	1-11	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-11	YES
	Claims		NO

2. Citations and explanations

1. The documents cited in the search report bear the consecutive numbering D1-D6; said numbering follows the order in which said documents appear in the search report and will be used throughout the rest of the procedure. Except where otherwise specified, the cited passage(s) for each document will be taken into consideration.

2. The amendments submitted with the fax dated 10-02-2005 do not appear to cause the subject matter of the application to be extended beyond the content of the application as filed. Consequently, they comply with the provisions of PCT Article 34(2)(b).

3. Novelty and inventive step (PCT Article 33(2) and (3))

3a. The subject matter of claims 1-5 is novel, since no prior art document describes an implantable structure for releasing an active ingredient, characterised in that lactic acid and/or a lactic acid oligomer is used as a plasticiser to reduce the transition temperature of the biodegradable polymer acting as a carrier for said structure. In

particular, D3 describes a plurality of plasticisers such as PEG or triacetin, but does not mention lactic acid as such. The same applies to D5.

The subject matter of claims 1-5 involves an inventive step:

D3 describes an implantable structure for the sustained and controlled release of an active ingredient. Said implantable structure contains

(a) a lactic acid and glycolic acid copolymer
(b) one or more plasticisers
(c) an active ingredient (see column 3, line 37 to column 5, line 41).

D3 teaches that elasticity and processability can be improved by reducing the transition temperature via the addition of a plasticiser.

The problem that the present application is intended to solve is that of providing an **alternative plasticiser**.

The solution proposed by the present application resides in using lactic acid or a lactic acid oligomer as such as a plasticiser. Since no other prior art document mentions or suggests using a plasticiser **having the same chemical entity** as the PALAG copolymer, namely lactic acid or its oligomer **as such**, the proposed solution involves an inventive step. Moreover, the use of a plasticiser of this type results in an implantable structure with the same biocompatibility and tolerance properties as the PALAG copolymer.

3b. The subject matter of claims 6-11 is novel, since no prior art document describes a method for making an implantable structure for the release of an active ingredient, characterised in that lactic acid and/or a lactic acid oligomer is used as a plasticiser and in that the compression moulding technique uses a preliminary transfer step carried out in a **transfer chamber**.

The subject matter of claims 6-11 involves an inventive step for the same reasons as those given in paragraph 3a above.
Moreover, D6, another document that could be seen as the closest prior art, describes a method for making implants that can be carried out by compression moulding (see pages 27-28), but said document does not provide any details concerning the production steps and, in particular, the use of a preliminary transfer step. Surprisingly, this step results in a uniform composite structure with coherent surfaces, which is non-porous and ensures the gradual and controlled release of the active ingredient (see also the current figures 13-15).

For the regional phase:

4. Contrary to the requirements of PCT Rule 5.1(a)(ii), the description does not outline the relevant prior art set forth in documents D3, D5 and D6 and does not cite these documents.

5. The new claims filed are considered to be admissible. Consequently, the applicant is invited to make the text of the description consistent with that of these claims. In doing so, care should be

taken, particularly as far as the introductory part setting forth the problem or the advantages is concerned, to avoid extending the subject matter of the application beyond the content of the application as originally filed.

To facilitate examination of the compliance of the amended application documents with the provisions of PCT Article 34(2)(b), the applicant is invited to identify clearly the amendments made, whether they consist of additions, replacements or deletions, and to specify those passages of the application as filed on which said amendments are based (cf. also, PCT Rule 66.8(a)).

As the case may be, said amendments may be made by hand on a copy of the relevant parts of the application as filed.